

REMARKSA. The rejection under 35 U.S.C. 112, first paragraph, for lack of enablement

In the office action, claims 8-22 were rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabling for combining data to produce corrected cardiac pressure data and transfer it to a remote center. Applicants respectfully traverse.

In the application at pages 12-13, there is the following description:

EPR 24 is generally carried by patient 12 or a belt implement 32 or is kept in close proximity to patient 12. EPR 24 is used to derive reference pressure data for use in combination with absolute pressure derived from Chronicle® (IMD 10). Various embodiments of this device are disclosed in U.S. Patent No. 6,152,885 issued to Taepke, which patent is incorporated herein by reference in its entirety. Similarly, U.S. Patent No. 5,810,735 to Halperin et al, discloses external patient reference sensors of internal sensors.

Enablement is a question of law to be determined as of the date of filing the application. The requirement is only for disclosure of sufficient information to enable one skilled in the art to make and use the claimed invention without undue experimentation. As to enablement for the production of corrected cardiac pressure data, the above quoted passage from the application directs one skilled in the art to combine reference pressure data with absolute pressure data in accordance with the Taepke and Halperin patents. To be noted is that Halperin is the primary reference cited and relied upon by the office in rejecting the claims for obviousness. Inherent in such a rejection is that Halperin enables the claimed subject matter. Halperin discloses the correction of internal pressure measurements via external measurements taken by an external pressure reference. It is inconsistent for the office action to reject the claims as being without an

enabling application disclosure and also to reject the claims based on a reference which is identified in the application.

Further, the Taepke patent discloses combining reference pressure data with absolute pressure data derived by an IMD and producing corrected pressure data. See col. 6, lines 16-39.

Halperin and Taepke disclose the use of an external barometric pressure sensor used in combination with an absolute pressure measurement obtained by an implanted cardiac pressure sensor. In both references, data is telemetered to a programmer. However, none of the cited references discloses a communication link between an information remote monitor (programmer) and a remote center over which corrected cardiac pressure data is transferred. With the claimed system, care providers at a remote location can monitor and manage patients with chronic disease. Such capability does not exist with the cited references. As pointed out, prior art methods, including Halperin and Taepke, of reviewing patient data and conducting clinical follow-ups on patients with implantable medical devices require a patient to go to a clinic or hospital.

The enablement rejection under §112, first paragraph, is without basis and should be withdrawn.

In regard to enablement for the transfer of corrected data to a remote center, applicants direct attention to the application at page 13 as follows:

Referring to Figure 2, IRM 20 is shown in telemetry communication with Chronicle® IMD 10. Generally, cardiac data is transmitted to IMD 10 via lead 14 as described hereinabove. During an uplink or a downlink session, telemetry communication is established between IMD 10 and IRM 20. Communication could be via antenna 18 or wireless communication such as RF signals 18' as is discussed

hereinbelow. Patient 12 triggers an uplink session by installing EPR 24 in a designated slot and push the start button. The microcontroller in IRM 20 will look for EPR 24 and if it confirms the existence of EPR 24 it will start downloading barometer data into IRM 20. Thereafter, telemetry is enabled and data will start being transmitted from IMD 10. When all the data from IMD 10 is telemetered down, then IRM 20 will try to transmit the data out via transmission line 26 which may include a phone line, a cable modem, an ISD line, a cable or equivalent wireless data transmission system to transfer the data to server 30.

Moreover, at pages 8 and 9 the description is given that:

The IRM may also, via a modem and other wireless communications media, transfer the data to a server or the remote center. In one embodiment, the IRM utilizes an integral modem to dial a server and transfer data via FTP, PPP and TC/PIP protocols.

Within the express description given in the application is a clear teaching to one skilled in the art as to available transfer mechanisms to enable the transfer of corrected data to a remote center.

The enablement rejection under §112, first paragraph, is without basis and should be withdrawn.

B. The rejection under §103 for obviousness

The rejection of the claims as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309) presents the same issues as were on appeal. The basis for the rejection is that Halperin discloses [*and enables*] an external barometric pressure sensor used in combination with an absolute pressure measurement obtained by an implanted

cardiac pressure sensor to produce corrected cardiac pressure data that is telemetered to a programmer. Halperin, however, fails to disclose a communication link between the programmer and a remote data center over which corrected cardiac pressure data is transferred. Krichen is relied upon as teaching a system of transferring information from an implanted medical device to a remote center.

Applicant has previously challenged the rejection as being improper for failing to identify any suggestion to combine the references. As Applicant has argued, Krichen only teaches the desire for an information format which can easily be interpreted and manipulated to allow for interpretation of data received as a "data dump" from an implanted medical device. Thus, the desire and any "suggestion" provided by Krichen are expressly restricted to a situation where an implantable medical device "dumps" its information to a programmer (col. 1, lines 46-53). But, the device of Halperin is not compatible with this type of data transfer.

The examiner has contended that Applicant's characterization of Krichen is in error because what Applicant relies upon is actually a description of the deficiency of the prior art. The passage identified by Applicant describes that in the prior art a data dump from an IMD to the programmer is made in a format which is not easily transferred via the Internet. (Col. 1, lines 46-59). Krichen provides a converter for information received from an IMD in an initial format, "such as a memory dump format." (Col. 2, lines 52-56). Thus, Krichen operates on the basis of a data dump from the IMD just as programmers previously operated. The data dump aspect of Krichen is therefore a carry-over from what had been done before. But, whereas the data was sent on by the programmer in the same format, Krichen converts the data to an XML format. Krichen further describes its operations on information that is a data dump from an IMD in column 12,

line 29 to column 13, line 15. Accordingly, there has been no misunderstanding by Applicant of the teachings of Krichen.

Thus, as discussed previously, the reach of the teachings of Krichen in regard to what has been termed as "a connection which facilitates transfer of info between programmer and computer" does not extend to information resident on a programmer that is not a "data dump" of implantable medical device information. The office action continues to indicate a failure to grasp the limited focus of Krichen and generalizes what Krichen contemplates in terms of communicating data from an implantable medical device to a remote location. The contention has also been made that Krichen's data transfer is compatible with Halperin. But, in view of the clear misunderstanding by the examiner of Krichen, that conclusion is suspect.

In applying the erroneous and overly broad characterization of the teachings of Krichen, the rejections of the claims, each of which is based on Halperin in combination with Krichen, fail to satisfy the required showing that there be a suggestion or motivation to combine the references. Further, even combining the references fails to result in the claimed subject matter. Thus, as to all claims 8-22, the rejections under §103 are in error, without basis and should be withdrawn.

C. Conclusion

Applicants submit that all pending claims are in condition for allowance and requests that a notice of allowance should be issued in due course.

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Respectfully submitted,

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